K132315

APR 18 2014

Traditional 510(k) Summary

A) Manufacturer:	Ergonomic Products, Inc., 767 Main Road, Suite One Westport, MA 02790 Phone Number: 1- 866-374-6487 Fax: 508-636-3680
Consultant:	Global Regulatory Compliance 767 Main Road, Suite One Westport, MA 02790 401-651-6513 Contact: Renee Gould
B) Date Prepared:	February 11, 2014
C) Device Name	Unit, Operative Dental
Proprietary Name:	Ergonomic Products Workstation
Device Regulations:	21 CFR 872.6640
Class:	II
Product Code:	EIA
Review Panel:	Dental
D) Predicates:	K000966 A-Dec 4631 Duo Delivery System, A-Dec, Inc. K935325 A-Dec Cascade 3072 Wallmount, A-Dec, Inc. K962071 Spirit S1/S2, Pelton & Crane, Co.

E) Device Description:

The Ergonomic Products Workstations provide a consolidated work area for the purpose of delivering air, water, vacuum, and electricity to handheld instruments, and is for use in a professional dental office by professional dental practitioners for administering care to dental patients. Ergonomic Products manufactures dental office delivery units in several formats, all using the same technology – Doctor Workstation, Hygiene Inwall Workstation, Universal Cart and Assistant Cart.

F) Intended Use:

The Ergonomic Products Workstation is a dental operative unit, which is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device is to be operated and used by dentists and other legally qualified professionals.

G) Comparison to Predicate Device(s):

	Ergonomic Products Workstations	A-Dec 4631 Duo Delivery System K000966 Cascade 3072 Wallmount K935325	
Product code	EIA	EIA	
Intended Use/ Indication for Use	The Ergonomic Products Workstation is a dental operative unit, which is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device is to be operated and used by dentists and other legally qualified professionals.	This device delivers air, water, vacuum and electricity to handheld instruments, for use in a professional dental office. It is designed to be used by professional dental practitioners for administering care to dental patients.	Are dent powered power to other der accessori operated other leg professio
Description	Doctor/assistant tables with instrument holder and mechanical enclosure with controls for air and water.	Doctor/assistant tables with instrument holder and mechanical enclosure with controls for air and water.	Doctor/a instrume mechani controls

Product Features/ Technological Characteristics	**Ergonomic Products Carts**	**A-Dec Carts**	**Pelton & Crane Spirit Carts**
Formats	Multiple including wallmount	Multiple including wallmount	Multiple including wallmount
Pivoting Delivery System	Standard	Standard	Standard
Control Block	Standard	Standard	Standard
Hand Piece Oil Collector	Standard	Standard	Standard
Wet Dry Foot Control	Optional	Standard	Standard
Wet Dry Panel Control	Standard	No	No
Solids Collector	Standard	Standard	Standard
Pivoting Instrument Arm	No	Standard	Standard
Autoclavable HVE and Saliva Ejector	Standard	Standard	Standard
Self Contained Water System	Standard	Standard	Standard
Water Quick Disconnect	Standard	Standard	Standard
Flow Control For QD	No	Standard	No
Cable Prewiring	Standard	Standard	Optional
Duplex Outlet	Standard Single	Standard	Standard
Height Adjustable Work Surface	Standard	Standard	Standard
Laminate Work Surface	No	Standard	Yes
Autoclavable syringe	Optional	Optional	Optional
Quick Disconnect for Air	Standard	Optional	Optional
Dual HVE	Optional	Optional	Optional
Quad Voltage Interoral Light Source	No	Optional	Optional
Programmable Chair Touchpad	No	Optional	Optional
Arm Mount Tray Holder	Solid Surface 2nd Tier	Optional	Standard
Solid Surface Worksurface	Standard	Optional	Standard
Computer Keyboard Tray	Standard	No	Optional
USB Outlet	Standard 2 Locations	No	No
Consumable Bin	Standard	No	No
Med Waste Bin	Standard	No	No
Bien Air handpiece integration	Optional	No	Optional
Piezo scaler	Optional	Optional	Optional

Substantial Equivalence Discussion

The Ergonomic Products Workstation has the same Intended Use, is a base for other dental devices and accessories, and has the same basic feature set as the predicate devices. Differences in format and/or options do not raise new issues of safety or effectiveness. Therefore, the Ergonomic Products Workstation is substantially equivalent to the predicate devices.

Performance

No specific performance standards promulgated for this device, and not specific performance testing was conducted.

Biocompatibility was not required as the Workstations have no patient contacting surfaces.

Conformity to Standards

- IEC 60601-1: 2005+C1:2009 +A2: 2010 Medical electrical equipment - Part **1:** General requirements for safety
- ISO 7494-1 First edition 2004-11-01 Dentistry - Dental units - Part 1: General requirements and test methods
- ISO 7494-2 First edition 2003-03-01 Dentistry - Dental units - Part 2: Water and air supply

Conclusion

The Ergonomic Products Workstation has the same Intended Use, is a base for other dental devices and accessories, and has the same basic feature set as the predicate devices. Therefore, the Ergonomic Products Workstation is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

Ergonomic Products, Inc.
C/O Ms. Renee Gould
Principal Consultant
Global Regulatory Compliance
240 Annette Ave
Woonsocket, RI 02895

Re: K132315
Trade/Device Name: Ergonomic Products Workstation
Regulation Number: 21 CFR 872.6640
Regulation Name: Unit, Operative Dental
Regulatory Class: II
Product Code: EIA
Dated: March 4, 2014
Received: March 13, 2014

Dear Ms. Gould:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by
Richard C. Chapman
Date: 2014.04.18
11:13:15 -04'00'

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Ergonomic Products Workstation

Indications for Use: The Ergonomic Products Workstation is a dental operative unit, which is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use X (21 CFR 801, Subpart D)	**OR**	Over-the-Counter Use _ (21 CFR 801, Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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